



## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PT-2032/05	<b>FOR FURTHER ACTION</b>  See Form PCT/IPEA/416	
International application No. PCT/BR2004/000237	International filing date (day/month/year) 25.11.2004	Priority date (day/month/year) 28.11.2003
International Patent Classification (IPC) or national classification and IPC C12P7/62, C08G63/89, C08G63/90		
Applicant PHB INDUSTRIAL S.A.et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains Indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  04.08.2005	Date of completion of this report  02.01.2006	
Name and mailing address of the international preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  van de Kamp, M  Telephone No. +31 70 340-2373  	

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-51 as originally filed

**Claims, Numbers**

1-44 as originally filed

**Drawings, Sheets**

1/1 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-44
	No: Claims	
Inventive step (IS)	Yes: Claims	1-44
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-44
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement (Continuation)**

**2.1 CITATIONS**

Reference is made to the following documents:

- D1:** NONATO R V ET AL: "Integrated production of biodegradable plastic, sugar and ethanol", APPL. MICROBIOLOGY & BIOTECHNOLOGY, vol. 57, no. 1-2, October 2001, pages 1-5
- D2:** ROSSELL C E V ET AL: "Production of biodegradable plastic ( PHB ), sugar and ethanol in a sugar mill" INTERNATIONAL SUGAR JOURNAL, vol. 104, no. 1243, 2002, pages 321-323

**2.2 NOVELTY (Art. 33(2) PCT)**

**D1** and **D2** disclose a process for recovering PHB from cellular biomass of bacteria obtained by fermentation, comprising steps of thermal inactivation, dilution with water, flocculation, separation and concentration, and multi-step extraction with medium-chain-length alcohols (**D1** page 2 right-hand column line 35-59, Table 1, and page 3 right-hand column line 10-37; **D2** page 321 center column). The process(es) disclosed in **D1** and **D2** yield PHB characterised by the parameters in Table 1 in both documents. The process as disclosed and claimed in independent **claim 1** of the current application differs from the process(es) disclosed in **D1** and **D2** by its sequence of steps, in particular steps involving (vigorous) agitation and (quick) heating (step i), (rapid) cooling (step iii), (cold) microfiltration (step iv), and washing, heating and agitation (step v). The resulting product has a molecular weight higher than the one disclosed in Table 1 of **D1** and **D2**, as well as advantageous properties in terms of smell and colour.

Hence, the present application satisfies the criterion set forth in Article 33(2) PCT as the subject-matter of **claims 1-44** appears to be new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

## **2.3 INVENTIVE STEP (Art. 33(3) PCT)**

The present application also satisfies the criterion set forth in Article 33(3) PCT because the subject-matter of **claims 1-44** is considered to involve an inventive step (Rule 65(1)(2) PCT). In view of **D1** and **D2**, which are considered as closest prior art to the subject-matter of independent **claims 1 and 44**, the problem to be solved can be summarised as the provision of methods for recovering PHA yielding products that are of high purity and of high molecular weight, environment-friendly and cost-effective. The solution as claimed in **claim 1** is not obvious in view of the prior art. Although individual steps of the recovering process may lack novelty and/or inventive step, the combination of steps is considered to involve an inventive step, and yielding a product with advantageous properties that could not be anticipated to result from the process of **claim 1**.

## **2.4 INDUSTRIAL APPLICABILITY (Art. 33(4) PCT)**

The subject-matter of **claims 1-44** satisfies the criterion set forth in Art. 33(4) PCT in conjunction with Rule 5(vi) PCT with respect to industrial applicability.

### **Re Item VIII**

#### **Certain observations on the international application (Continuation)**

- 1** The use of adjectives and adverbs in **claim 1** leads to unclarities, contrary to Art. 6 PCT. The meaning of the following adjectives or adverbs in **claim 1** is not clear: vigorous (agitation), quick (heating), rapidly (cooling), sufficient (to) substantially (precipitate), cold (microfiltration), adequate (to obtain a suspension), high (porosity), easily (shearable), rapidly (break). A proper understanding of at least some of these adjectives and adverbs appears essential for comprehending what belongs to the scope of the subject-matter of **claim 1**. Further claims also contain adjectives and/or adverbs (e.g., low, rapid(ly), sufficient(ly), e.g., in **claims 31-33, 41, 42**) that render the subject-matter unclear.
- 2** The claims contain many terms and/or expressions that are not clear, contrary to Art. 6 PCT, such as 'PHA solvent' and 'provoke' (**claim 1** step i, claim 2), 'promote' (**claim**

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1 step v), 'primordially (?) composed by' (**claim 4**), 'to a concentration to the range of...' (**claim 27**), 'by weight of the suspension' (**claim 36**), 'particle average size' (**claim 43**).

- 3** **Claim 44** is currently in the form of a product-by-process claim. It is thus unclear, contrary to Art. 6 PCT, what the technical features are that make it novel and inventive over PHA as disclosed in the prior art (which, e.g., discloses PHAs with molecular weights higher than 400,000 Da).